FREEDOM OF INFORMATION SUMMARY

Supplemental NADA

131-675

Safe-Guard® Dewormer 20% Type A medicated article
(fenbendazole)

An additional claim for Safe-Guard® Dewormer 20% Type A medicated article adding: "for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses.

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

a. NADA Number: 131-675

b. Sponsor: Intervet, Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966-0318

Drug Labeler Code: 057926

c. Established Name: fenbendazole

d. Proprietary Name: Safe-Guard® Dewormer 20% (fenbendazole) Type A Medicated Article

e. Dosage Form: Type A medicated article

f. How Supplied: 25 lb. (11.34 kg) bag

g. How Dispensed: Over the counter (OTC)

h. Amount of Active Ingredient: 200 grams per kilogram (90.7 grams per pound)

i. Route of Administration: Oral

j. Species/Class: Horses/Equine

k. Recommended Dosage: For the control of large strongyles, small strongyles, and pinworms, the recommended dose is 5 mg fenbendazole per kg body weight (2.27 mg/lb) in a one day treatment. For the control of ascarids, the recommended dose is 10 mg fenbendazole per kg body weight (4.54 mg/lb) in a one day treatment.

Regular deworming at intervals of six to eight weeks may be required due to the possibility of reinfection. A veterinarian should be consulted for assistance in the diagnosis, treatment, and control of parasitism.

Safe-Guard® Dewormer 20% (fenbendazole) Type A medicated article should be diluted before addition to the ration. A dilution of one part of Safe-Guard®

Type A medicated article and nine parts of grain carrier is the suggested working premix. The working premix is then blended with the complete feed mixture. Both the working premix and complete feed should be thoroughly mixed to ensure complete and uniform distribution of the product.

l. Pharmacological Category: Anthelmintic

m. Indications: Safe-Guard® Dewormer 20% (fenbendazole) Type A medicated article is indicated for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*, *Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses.

n. Effect of Supplement: This supplement to NADA 131-675 provides for a new claim for control of gastrointestinal worms in horses [large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*, *Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*)].

II. EFFECTIVENESS

A. Dosage Characterization:

The dose and duration of fenbendazole for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*, *Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*) at 5 mg/kg (2.27 mg/lb) body weight as a one day treatment, and for the control of ascarids (*Parascaris equorum*) at 10 mg/kg (4.54 mg/lb) as a one day treatment in horses, was established in the original approval of 10% fenbendazole suspension under NADA 128-620.

B. Substantial Evidence:

Study Title: Clinical Endpoint Bioequivalence Study in Equines to Compare the Effectiveness of Fenbendazole Pellets (0.5%) and Fenbendazole Suspension (10%) Administered Orally

Clinical Investigator: Dr. Allan J. Paul, DVM, MS, University of Illinois, College of Veterinary Medicine, 2001 South Lincoln Avenue, Urbana, Illinois 61801

Purpose of Study: To demonstrate bioequivalence of two orally administered formulations of fenbendazole at a dose rate of 5.0 mg/kg body weight in horses naturally infected with adult large and small strongyles.

Study Design: A clinical endpoint study was conducted in horses naturally infected with large and small strongyles, to establish the bioequivalence of the proposed 20% fenbendazole Type A medicated article (fed as a 0.5% fenbendazole top dress, a Type C medicated feed) to an approved 10% fenbendazole suspension (Panacur® NADA 128-620).

Thirty (30) horses were ranked in descending order on a basis of fecal egg counts (eggs per gram, [epg]) and assigned to replicate groups of three (3) horses. The presence of large and small strongyles were confirmed by coproculture. Horses within each replicate were randomly assigned to the treatment and control groups. Horses were housed three per pen by replicate for the duration of the study. The two treatment groups and the control group each comprised 10 horses. The mixed breed horses (17 females, 13 males) were one to four years of age and weighed between 214 and 384 kg at the start of the study. The 10% suspension formulation was administered orally by dose syringe and the 0.5 % pellets were top dressed on a feed container mixed with oats. Both fenbendazole formulations were given at a dose rate of 5.0 mg/kg body weight as a single oral dose. The control group received non-medicated pellets.

Data collected during the study included: time and amount of formulation consumed or dosed, reaction of animals to dosing and during treatment, fecal egg counts before the start of the study and at necropsy, and post-mortem counts of adult stages of large strongyles, small strongyles and pinworms from the contents of the large intestine.

Effectiveness was calculated as the percentage (%) reduction in geometric mean (GM) worm burdens of the fenbendazole treated groups relative to the control animals as follows:

$$\text{Effectiveness \%} = \frac{GMc - GMt}{GMc} \times 100$$

GMc = Geometric mean number of parasites in control horses.

GMt = Geometric mean number of parasites in treated horses

Study Results: Fecal egg output was significantly reduced by >98% in both treatment groups ($P<0.0001$). Effectiveness against the pivotal parasites, namely, *S. edentatus*, *S. vulgaris* and cyathostomes was 97-100% for both formulations. Differences in effectiveness between the two formulations were not significant thus demonstrating bioequivalence. There were no adverse reactions related to the treatments.

Strongyle adult worm counts of the target species for determining bioequivalence of the two formulations, namely cyathostomes, *Strongylus edentatus,* and *Strongylus vulgaris,* at postmortem were analyzed for differences using Analysis of Variance Method (PROC GLM) at the 5% significance level. The effectiveness of the two formulations of fenbendazole for controlling these parasites was not significantly different, thus demonstrating that the two formulations are bioequivalent. The results of the effectiveness study are presented below.

Table 1 - Group Geometric Mean Fecal Egg Counts (epg)[1] Before & After Treatment & Effectiveness (%)

Group	Number Animals	Pre-Treatment Geometric mean	Post Treatment Geometric Mean	% Reduction (pre/post treatment)
0.5% Pellets	10	146.41	1.42	99.03
10% Suspension	10	146.52	2.71	98.15
Control	10	151.08	312.91	-

(1) epg = eggs per gram

Table 2: Group Geometric Mean Adult Worm Counts of Treated & Control Horses at Necropsy & Efficacy(%): Pivotal Data *

Parasite	Treatment Group	Geometric Mean	% Reduction	*P*-value Suspension vs. Pellets
Small Strongyles (Cyathostomes)	1. Pellets 2. Suspension 3. Control	1.50 0.64 101.28	98.52 99.37 -	0.5386
Strongylus edentatus	1. Pellets 2. Suspension 3. Control	0.00 0.00 18.18	100 100 -	1.00
Strongylus vulgaris	1. Pellets 2. Suspension 3. Control	0.28 0.00 13.67	97.95 100 -	0.6625

*70% or more of the control horses infected

Study Conclusions:
A 0.5 % fenbendazole pelleted ration, formulated from the 20% Type A medicated article was readily consumed by horses and was well tolerated. Effectiveness against the target adult parasites, namely, Cyathostomes, *S. edentatus* and *S. vulgaris* was in excess of 97%. Analysis of the parasite burdens of the horses given the pellet formulation and those given the 10% suspension formulation showed that there were no significant differences in anthelmintic activity between the two formulations, thus demonstrating that both formulations were clinically bioequivalent.

III. TARGET ANIMAL SAFETY

The safety of fenbendazole administration to horses was established in the original approval for the 10% fenbendazole oral suspension under NADA 128-620. No new safety studies were conducted in support of this supplemental approval.

IV. HUMAN SAFETY

Data on human safety pertaining to the consumption of drug residues in food were not required for approval of this NADA. This drug is labeled for use in horses which are non-food animals. The following "Residue Warning" statement appears on the product label: "Do not use in horses intended for food." Regarding human safety relative to possession, handling and administration, a "Warning" statement appears on the product label as follows: "Keep this and all medication out of the reach of children. Not for use in humans."

V. AGENCY CONCLUSIONS

The data in support of this NADA comply with the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21CFR Section 514 of the implementing regulations. The data demonstrate that Safe-Guard® Dewormer (fenbendazole) 20% Type A medicated article is safe and effective when used under labeled conditions.

The drug is labeled for over the counter use. Routine deworming of horses is a widely accepted and recommended practice performed by the layperson. The product labeling contains detailed information on use deemed to be adequate for the layperson.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non food producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies only to the new claim for control of gastrointestinal worms in horses, for which the supplemental application was approved.

VI. ATTACHMENTS

Labeling is attached as indicated below:

Type A medicated article bag label
Type B medicated feed specimen (Blue Bird) label
Type C medicated feed specimen (Blue Bird) label

000010

Safe-Guard® (fenbendazole)

Dewormer

20% Type A Medicated Article

CATTLE: Dairy and Beef Cattle • SWINE: Growing pigs, gilts, pregnant sows, and boars • Horses

Zoo and Wildlife Animals

Growing Turkeys

ACTIVE DRUG INGREDIENT: Fenbendazole 200 grams per kilogram (90.7 grams per pound).
INERT INGREDIENTS: Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil or Soybean Oil.

MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS FOR USE IN MANUFACTURED FEEDS ONLY

CATTLE: Dairy and Beef Cattle

FOR THE REMOVAL AND CONTROL OF:

Lungworms: *(Dictyocaulus viviparus).*

Stomach worms: Barberpole worms *(Haemonchus contortus)*, brown stomach worms *(Ostertagia ostertagi)*, small stomach worms *(Trichostrongylus axei)*.

Intestinal worms: Hookworms *(Bunostomum phlebotomum)*, thread-necked intestinal worms *(Nematodirus helvetianus)*, small intestinal worms *(Cooperia punctata & C. oncophora)*.

Bankrupt worms. *(Trichostrongylus colubriformis)*

Nodular worms: *(Oesophagostomum radiatum)*

DOSAGE REGIMEN:

5 mg fenbendazole per kg body weight in a one (1) day treatment (2.27 mg fenbendazole per pound)

EXAMPLE OF MIXING AND FEEDING RATES FOR SAFE-GUARD® 20% TYPE A MEDICATED ARTICLE

For a one (1) day treatment, mix the following quantities of SAFE-GUARD® 20% Type A Medicated Article into the daily ration according to body weight and number of cattle per pen

Amount of SAFE-GUARD® 20% Type A Medicated Article for:

Body Weight		10 Cattle		20 Cattle		100 Cattle	
lbs.	kg	g	lbs.	g	lbs	g	lbs
200	90.7	23	0.05	46	0.10	230	0.5
400	181.4	46	0.10	92	0.20	460	1.0
600	272.2	69	0.15	138	0.30	690	1.5
800	362.9	92	0.20	184	0.40	920	2.0
1000	453.6	114	0.25	228	0.50	1140	2.5
1400	635.0	160	0.35	320	0.70	1600	3.5

Feed as the sole ration for one (1) day. No prior withdrawal of feed or water necessary. When feed containing SAFE-GUARD® has been fed for 1 day and blended according to the above rates based on weight and number of cattle treated, a total intake of 2.27 mg fenbendazole per pound of body weight is assured. Cattle feed containing SAFE-GUARD® can be fed pelleted or as meal.

Under conditions of continued exposure to parasites, retreatment may be needed after 4-6 weeks.

GENERAL USE DIRECTIONS

It is recommended that SAFE-GUARD® 20% Type A Medicated Article be diluted before addition to the feed. A dilution of one part of SAFE-GUARD® 20% Type A Medicated Article and nine parts of grain carrier is the suggested working premix. The working premix is then blended with the complete feed mixture. Thoroughly mix both working premix and complete feed to ensure complete and uniform distribution of the SAFE-GUARD® 20% Type A Medicated Article.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS, or for assistance contact customer service at 1-800-441-8272.

RESIDUE WARNING: Cattle must not be slaughtered within 13 days following last treatment. There are no known contraindications to the use of the drug in cattle. For dairy cattle, there is no milk withdrawal period.

SWINE: Growing pigs, gilts, pregnant sows, and boars

FOR THE REMOVAL AND CONTROL OF:

Lungworms *(Metastrongylus apri, Metastrongylus pudendotectus)*

Gastrointestinal worms Large roundworms, adult and larvae (L_3, L_4 stages – liver, lung, intestinal forms) *(Ascaris suum)*; nodular worms *(Oesophagostomum dentatum, O. quadrispinulatum)*; small stomach worms *(Hyostrongylus rubidus)*; whipworms, adult and larvae (L_2, L_3, L_4 stages - intestinal mucosal forms) *(Trichuris suis)*

Kidney worms Adult and larvae *(Stephanurus dentatus)*

DOSAGE REGIMEN

9 mg fenbendazole per kg body weight (4.08 mg fenbendazole per pound) to be fed as the sole ration over a period of 3 to 12 days

EXAMPLE OF MIXING AND FEEDING RATES FOR SAFE-GUARD® 20% TYPE A MEDICATED ARTICLE

Average daily feed consumption		Amount of SAFE-GUARD® 20% Type A Medicated Article added to each ton of swine feed based on weight and average feed consumption					
		Treatment Period					
Pig Wt.	lbs. of	3 Days		6 Days		12 Days	
(lbs.)	Feed	lbs.	Grams	lbs	Grams	lbs.	Grams
30	2.25	0.40	182	0.20	91	0.10	46
50	3.20	0.47	213	0.24	107	0.12	54
75	4.25	0.53	241	0.27	121	0.14	61
100	5.30	0.57	258	0.29	129	0.15	65
150	6.80	0.66	301	0.33	151	0.17	76
200	8.00	0.75	341	0.38	171	0.19	86

Feed as the sole ration for three (3) to twelve (12) consecutive days. No prior withdrawal of feed or water necessary. When feed containing SAFE-GUARD® has been blended according to the above rates based on pig weight and average daily feed consumption, and is then fed for 3-12 days, a total intake of 9 mg fenbendazole per kilogram body weight (4.08 mg fenbendazole per pound) is assured. Swine feeds containing SAFE-GUARD® can be fed pelleted or as meal.

GENERAL USE DIRECTIONS

It is recommended that SAFE-GUARD® 20% Type A Medicated Article be diluted before addition to the feed. A dilution of one part of SAFE-GUARD® 20% Type A Medicated Article and nine parts of grain carrier is the suggested working premix. The working premix is then blended with the complete feed mixture. Thoroughly mix both working premix and complete feed to ensure complete and uniform distribution of the SAFE-GUARD® 20% Type A Medicated Article.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS, or for assistance contact customer service at 1-800-441-8272.

RESIDUE INFORMATION. There is no pre-slaughter withdrawal period as SAFE-GUARD® can be fed to day of slaughter.

Horses

FOR THE CONTROL OF:

Large strongyles: (Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus spp.) **Small strongyles:** (Cyathostomum spp., Cylicocyclus spp., Cylicostephanus spp.) **Pinworms** (Oxyuris equi) **Ascarids:** (Parascaris equorum)

DOSAGE REGIMEN:

For the control of large strongyles, small strongyles, and pinworms the recommended dose is 5 mg fenbendazole per kg body weight (2.27 mg fenbendazole per pound) in a **ONE (1) DAY** treatment.

For the control of ascarids the recommended dose is 10 mg fenbendazole per kg body weight (4.54 mg fenbendazole per pound) in a **ONE (1) DAY** treatment.

All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed.

EXAMPLE OF MIXING AND FEEDING RATES FOR SAFE-GUARD® 20% TYPE A MEDICATED ARTICLE

For a **ONE (1) DAY** treatment, mix the following quantities of SAFE-GUARD® Type A Medicated Article into the daily ration according to body weight and dose.

Amount of SAFE-GUARD® 20% Type A Medicated Article		
Body Weight	For dose of 2.27 mg fenbendazole/lb body weight	For dose of 4.54 mg fenbendazole/lb body weight
lbs	grams	grams
200	2.27	4.54
400	4.54	9.08
600	6.81	13.62
800	9.08	18.16
1000	11.35	22.70
1200	13.62	27.24

Feed for **ONE (1) DAY** as above. No prior withdrawal of feed or water is necessary. Horse feed containing SAFE-GUARD® can be fed pelleted or as a meal.

Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection.

GENERAL USE DIRECTIONS

It is recommended that SAFE-GUARD® Type A Medicated Article be diluted before addition to the feed. A dilution of one part of SAFE-GUARD® Type A Medicated Article and nine parts of grain carrier is the suggested working premix. The working premix is then blended with the complete feed mixture. Thoroughly mix both working premix and complete feed to ensure complete and uniform distribution of the SAFE-GUARD® Type A Medicated Article.

ANIMAL SAFETY There are no known contraindications for the use of fenbendazole in horses. Side effects associated with SAFE-GUARD® (fenbendazole) could not be established in well-controlled safety studies in horses with single doses as high as 454 mg/lb (1,000 mg/kg) and 15 consecutive daily doses of 22.7 mg/lb (50 mg/kg).

SAFE-GUARD® (fenbendazole) has been evaluated for safety in pregnant mares during all stages of gestation with doses as high as 11.4 mg/lb (25 mg/kg) and in stallions with doses as high as 11.4 mg/lb (25 mg/kg). No adverse effects on reproduction were detected.

WARNING: KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. NOT FOR USE IN HUMANS. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS, or for assistance contact customer service at 1-800-441-8272.

RESIDUE WARNING. Do not use in horses intended for food.

SEE OTHER SIDE FOR ZOO AND WILDLIFE ANIMALS AND GROWING TURKEYS

CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM.

Net Weight 25 pounds (11.34 kg)

Distributed by: Intervet Inc.
Millsboro DE 19966

Intervet

NADA # 131-675, Approved by FDA

784625-A

Safe-Guard®

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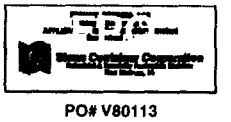

PO# V80113

Safe-Guard® (fenbendazole)

Dewormer

20%Type A Medicated Article

CATTLE: Dairy and Beef Cattle

SWINE

Growing pigs, gilts, pregnant sows, and boars

Horses

Zoo and Wildlife Animals

Growing Turkeys

ACTIVE DRUG INGREDIENT: Fenbendazole 200 grams per kilogram (90.7 grams per pound).
INERT INGREDIENTS: Roughage Products or Roughage Products and Calcium Carbonate; and Mineral Oil or Soybean Oil.

MUST BE MIXED BEFORE FEEDING ACCORDING TO DIRECTIONS AND PERMITTED CLAIMS
FOR USE IN MANUFACTURED FEEDS ONLY

Zoo and Wildlife Animals

FOR THE REMOVAL AND CONTROL OF:
Internal parasites in hoofed zoo and wildlife animals (see dosage section for specific parasites, animal species and required doses)

DOSE/DOSAGE REGIMENS

Host Animal	Recommended Treatment for	mg Fenbendazole/kg Body Wt./Day x Days of Treatment
Bighorn Sheep *(Ovis canadensis canadensis)*	**lungworms:** *(Protostrongylus spp.)*	10 mg x 3
Feral Swine *(Sus scrofa)*	**kidney worms:** *(Stephanurus dentatus)*, **roundworms:** *(Ascaris suum)* **nodular worms:** *(Oesophagostomum dentatum)*	3 mg x 3
Ruminants - subfamily antilopinae: Persian gazelles *(Gazella subgutturosa subgutturosa)* Addra gazelle *(Gazella dama ruficollis)* Slenderhorn gazelle *(Gazella leptoceros)* Kenya impala *(Aepyceros melampus rendilis)* Roosevelt's gazelle *(Gazella granti roosevelti)* Indian blackbuck *(Antilope cervicapra)* Mhorr gazelle *(Gazella dama mhorr)* Thomson's gazelles *(Gazella thomsoni thomsoni)* **Ruminants - subfamily hippotragina:** Addax *(Addax nasomaculatus)* Angolan roan antelope *(Hippotragus equinus cottoni)* Fringed-ear oryx *(Oryx gazella callotis)* Arabian oryx *(Oryx leucoryx)* **Ruminants - subfamily caprinae:** Armenian mouflon *(Ovis orientalis gmelini)* Russian saiga *(Saiga tatarica)*	**small stomach worms:** *(Trichostrongylus spp.)*, **thread-necked intestinal worms:** *(Nematodirus spp.)*, **barberpole worms:** *(Haemonchus spp.)*, **whipworms:** *(Trichuris spp.)*	2.5 mg x 3

It is recommended that the user exercise judgmental expertise as needed for retreatment within six (6) weeks This would depend upon the conditions of continued exposure to parasites, condition of treated animals, and ambient temperatures

GENERAL USE DIRECTIONS:
SAFE-GUARD® 20% Type A Medicated Article must be mixed according to directions and at correct concentrations based upon the species to be treated It is recommended that SAFE-GUARD® 20% Type A Medicated Article be diluted before addition to the feed. The correct proportions of premix and feed ingredients should be established for blending into the complete feed This premix and feed ingredient combination should be thoroughly and uniformly mixed with the complete feed

SAFE-GUARD® 20% Type A Medicated Article can be fed to adult and young animals either in a mash or pelleted feed No prior withdrawal of feed or water is necessary

ANIMAL SAFETY: No contraindications for the use of fenbendazole in a zoo environment have been established Administration to breeding and pregnant ruminants at 2 to 22 times the recommended dose has had no apparent adverse effect

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN NOT FOR USE IN HUMANS The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information To report adverse effects, obtain an MSDS, or for assistance contact customer service at 1-800-441-8272

RESIDUE WARNING: Do not use 14 days before or during the hunting season

Growing Turkeys

FOR THE REMOVAL AND CONTROL OF:
Gastrointestinal worms: Roundworms, adults and larvae *(Ascaridia dissimilis)*; Cecal worms, adults and larvae *(Heterakis gallinarum)*, an important vector of *Histomonas meleagridis* (Blackhead)

DOSAGE REGIMEN:
14.5 g fenbendazole/ton of feed, to be fed as the sole ration for 6 days

GENERAL USE DIRECTIONS:
It is recommended that SAFE-GUARD® 20% Type A Medicated Article be diluted before addition to the feed A dilution of one part of SAFE-GUARD® 20% Type A Medicated Article and nine parts of grain carrier is the suggested working premix The working premix is then blended with the complete feed mixture Thoroughly mix both working premix and complete feed to ensure complete and uniform distribution of the SAFE-GUARD® 20% Type A Medicated Article

FEEDING DIRECTIONS:
Medicated feed containing fenbendazole should be fed as the sole ration for six (6) consecutive days to growing turkeys only No prior withdrawal of feed or water necessary Growing turkey feeds containing SAFE-GUARD® can be fed pelleted or as meal

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN NOT FOR USE IN HUMANS The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information To report adverse effects, obtain an MSDS, or for assistance contact customer service at 1-800-441-8272.

RESIDUE INFORMATION: There is no pre-slaughter withdrawal period as SAFE-GUARD® can be fed to day of slaughter

SEE OTHER SIDE FOR CATTLE, SWINE AND HORSES

CONSULT YOUR VETERINARIAN FOR ASSISTANCE IN THE DIAGNOSIS, TREATMENT, AND CONTROL OF PARASITISM

Net Weight 25 pounds (11.34 kg)

Distributed by Intervet Inc
Millsboro, DE 19966

Intervet

NADA # 131-675, Approved by FDA

784625-A

Safe-Guard®

Net weight on bag or invoice

Horse Feed
Fenbendazole Horse Dewormer
Type B Medicated Feed

Indications
For the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*) and ascarids (*Parascaris equorum*).

Active drug ingredient
Fenbendazole 10,000-17,740 g/ton

Ingredients
Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Guaranteed Analysis

Crude Protein	Not less than_____%
Crude Fat	Not less than_____%
Crude Fiber	Not more than____%
Calcium	Not less than_____%
	Not more than____%
Phosphorus	Not less than_____%
Copper	Not less than____ ppm
Selenium	Not less than____ ppm
Zinc	Not less than____ ppm
Vitamin A (if added)	Not less than____ IU/lb

Mixing directions
Mix 512 to 908 pounds of Type B medicated feed with 1,488 to 1,092 pounds of feed ingredients to manufacture Type C medicated feed containing 4,540 grams (0.5%) fenbendazole per ton. The resulting Type C feed is to be fed at the rate of 0.1 or 0.2 pounds per 100 pounds of body weight to provide 2.27 or 4.54 mg fenbendazole per pound of body weight.
The recommended dose is 5 mg per kg body weight (2.27 mg fenbendazole per pound) in a **ONE (1) DAY** treatment for large strongyles, small strongyles and pinworms. For ascarids the recommended dose is 10 mg fenbendazole per kg body weight (4.54 mg fenbendazole per pound) in a **ONE (1) DAY** treatment.

Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Warning
Do not use in horses intended for food.

Manufactured by
Blue Bird Feed Mill
Robin, Indiana

Lot No.

Net weight on bag or invoice

Horse Feed
Fenbendazole Horse Dewormer

Type C Medicated Feed

Indications
For the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*) and ascarids (*Parascaris equorum*).

Active drug ingredient
Fenbendazole 4,540 g/ton (0.5%)

Ingredients
Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Guaranteed Analysis

Crude Protein	Not less than_____%
Crude Fat	Not less than_____%
Crude Fiber	Not more than____%
Calcium	Not less than_____%
	Not more than____%
Phosphorus	Not less than_____%
Copper	Not less than____ ppm
Selenium	Not less than____ ppm
Zinc	Not less than____ ppm
Vitamin A (if added)	Not less than____ IU/lb

Feeding directions
The recommended dose is 5 mg per kg body weight (2.27 mg fenbendazole per pound) in a **ONE (1) DAY** treatment for large strongyles, small strongyles and pinworms. For ascarids the recommended dose is 10 mg fenbendazole per kg body weight (4.54 mg fenbendazole per pound) in a **ONE (1) DAY** treatment. Feed at the rate of 0.1 or 0.2 pounds per 100 pounds of body weight to provide 2.27 or 4.54 mg fenbendazole per pound of body weight.
All horses must be eating normally to ensure that each animal consumes an adequate amount of medicated feed.

Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Warning
Do not use in horses intended for food.

Manufactured by
Blue Bird Feed Mill
Robin, Indiana

Lot No.